

**510K Summary of Safety and Effectiveness**  
**April 7, 2003**

**JUL 08 2003**

1. Sponsor Name

Medical Innovative Products  
205 Royal Oak Ave.  
Pittsburgh, PA 15235  
Telephone: (412)-244-9205  
Contact Individual: Michael Swartz

2. Device Name

Proprietary Name: NGT Nasogastric Thermistor  
Common/Usual Name: Nasogastric Tube

3. Identification of Predicate or Legally Marketed Device

- Bard Nasogastric Sump Tube manufactured by C.R. Bard cleared under K960176
- Argyle Salem Sump Tube manufactured by Sherwood Medical cleared under K935781
- Mon-a-therm Esophageal Stethoscope with temperature sensor manufactured by Mallinckrodt cleared under K914887

4. Device Description

The NGT Nasogastric Tube is made of a plastic material, contains three lumens, a main suction lumen, a smaller vent lumen, and a still smaller temperature thermistor lumen. The primary suction lumen is used for drainage, the second vent lumen provides an air inlet as a mechanism to break suction minimizing the potential for tube blockage secondary to mucosal tissue invagination into the side holes of the primary lumen. The device is intended to be used with a standard suction source to facilitate drainage.

5. Intended Use

The NGT is intended for gastric decompression, gastric lavage, gastric suction, administration of nutritional supplements and medication, and to monitor core temperature.

6. Comparison of Technological Characteristics

The NGT Nasogastric Tube has similar technological characteristics to the Bard Nasogastric Sump Tube and the Argyle Salem Sump Tube in that the materials are the same, the sizes available are within the range of sizes currently available, but the NGT Nasogastric Tube incorporates a temperature monitoring capability. This temperature monitoring capability is similar to the Mallinckrodt Mon-a-therm Esophageal Stethoscope with temperature sensor. However, the NGT Nasogastric Tube incorporates this temperature thermistor into a third lumen whereas the other predicates all have 2 lumens.

The differences in the configurations of each of the devices do not affect the ability of the device to suction gastric fluids. Each of the devices requires monitoring by the clinical staff to assure proper nasogastric tube function. Each of the devices uses the same operating principal.

7. Performance Testing

Bench testing was performed on the NGT to demonstrate equivalency.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 08 2003

Medical Innovative Products  
c/o Ms. Debbie Iampietro  
QRC Consulting  
7 Tiffany Trail  
HOPKINTON MA 01748

Re: K022558

Trade/Device Name: NGT NasoGastric Thermistor  
Regulation Number: 21 CFR §876.5980  
Regulation Name: Gastrointestinal tube and accessories  
Regulatory Class: II  
Product Code: 78 KNT  
Dated: April 7, 2003  
Received: April 9, 2003

Dear Ms. Iampietro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

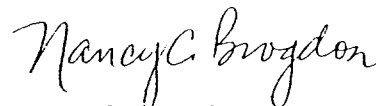
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K022558

Device Name: NGT Nasogastric Thermistor

Indications For Use:

The NGT is intended for gastric decompression, gastric lavage, gastric suction, administration of nutritional supplements and medication, and to monitor core temperature.

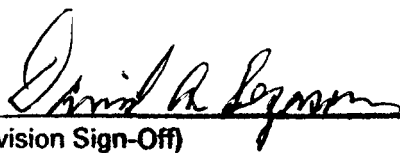
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K022558